Initial REMS Approved: 12/21/2012
Modified REMS: 06/2014

NDA 203441 GATTEX®
(Teduglutide [rDNA origin]) for Injection

NPS Pharmaceuticals, Inc.

550 Hills Drive

Bedminster, NJ07921

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

To inform prescribers and patients about the risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders associated with GATTEX.

II. REMS ELEMENTS

A. Communication Plan

NPS will implement a communication plan to support implementation of the REMS. The communication plan materials will comprise:

1. **A Dear Healthcare Professional letter** to gastroenterologists, colorectal and gastrointestinal tract surgeons. In order to facilitate prescriber training and education, this initial letter will be distributed within 60 days of approval of GATTEX or at the time of product launch, whichever is sooner. The letter will be sent again at 12 and 24 months after product approval. NPS will also identify and send the DHCP letter to all other GATTEX prescribers within 60 days of the date of initial prescription, and again at 12 and 24 months after their initial prescription. This letter will be distributed via direct mail or electronic delivery and will be accessible via the GATTEX REMS website (www.GATTEXREMS.com). A copy of the Full Prescribing Information and a Medication Guide will be included in the Dear Healthcare Professional letter.

2. **A Dear Professional Society letter** to the leadership of the professional organizations listed below requesting that the letter be provided to the members of these professional organizations. The Dear Professional Society letter will be disseminated via direct mail or electronic delivery within 60 days of approval of GATTEX or at the time of product launch, whichever is sooner. The letter will be sent again at 12 and 24 months

after product approval. A copy of the Full Prescribing Information and a Medication Guide will be included in the Dear Professional Society letter.

i. American Society for Parenteral and Enteral Nutrition
ii. American Gastroenterological Association
iii. American College of Gastroenterology
iv. Society for Surgery of the Alimentary Tract
v. American Society of Colon and Rectal Surgery
vi. American Board of Physician Nutrition Specialists (ABPNS)

The Dear Healthcare Professional letter and the Dear Professional Society letter are part of the REMS and are appended.

The Dear Healthcare Professional letter and the Dear Professional Society letter will be provided to MedWatch at the same time they are provided to the healthcare professionals and the professional society leadership.

B. Elements To Assure Safe Use

1. Healthcare providers who prescribe GATTEX will receive training.

    a. NPS Pharmaceuticals, Inc. will ensure that training is made available to healthcare providers who prescribe GATTEX. Training will consist of the Prescriber Education Slide Deck.

    b. NPS Pharmaceuticals, Inc. will ensure that retraining is made available to prescribers who have not written a prescription for Gattex within 12 months of completing REMS training.

    c. Each prescriber will be provided with the **Prescriber Education Slide Deck** which will include the following information:

        i. The risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth associated with GATTEX.

        ii. The serious risk of gastrointestinal obstruction associated with GATTEX.

        iii. The serious risk of biliary and pancreatic disorders associated with GATTEX.

        iv. The recommended screening colonoscopy, follow-up colonoscopy, and monitoring laboratory tests

    d. NPS will ensure that the Prescriber Education Slide Deck will be available in hard copy and on the GATTEX REMS website.

    NPS will ensure that prescribers can report that they have completed the Prescriber Education Slide Deck.

e. NPS will maintain a list of healthcare providers (HCPs) who have completed the Prescriber Education Slide Deck.

f. In order to facilitate patient and/or caregiver education about GATTEX, NPS will ensure that the What You Need to Know About Gattex Treatment: A Patient and Caregiver Counseling Guide will be available for prescribers to use to counsel patients considering GATTEX therapy about the possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders associated with GATTEX, as well as the recommended screening colonoscopy, follow-up colonoscopy and monitoring laboratory tests.

g. NPS will ensure that all educational materials listed in or appended to the GATTEX REMS will be available through the GATTEX REMS website, www.GATTEXREMS.com.

h. The following materials are part of the GATTEX REMS and are appended:

- *Prescriber Education Slide Deck*
- *What You Need to Know About Gattex Treatment: A Patient and Caregiver Counseling Guide*
- *GATTEX REMS Website Screenshots*

These materials will also be available by calling NPS Pharmaceuticals, Inc. at 1-855-5GATTEX or 1-855-542-8839.

C. Timetable for Submission of Assessments

NPS will submit REMS assessments to FDA at 12 months from the date of initial approval of the REMS and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. NPS will submit each assessment so that it is received by the FDA on or before the due date.

GATTEX Dear HealthCare Professional Letter

[Date]

IMPORTANT DRUG WARNING

Subject: Risk of possible acceleration of neoplastic growth and enhancement of colon polyp growth, GI obstruction, biliary and pancreatic disorders with GATTEX® (teduglutide)

Dear Healthcare Professional:

The purpose of this letter is to remind you about serious risks associated with GATTEX® (Teduglutide [rDNA origin]) for Injection and need for continuous monitoring for these risks.

Gattex is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of GATTEX outweigh the potential risks.

Serious Risks of GATTEX

Possible acceleration of neoplastic growth and enhancement of colon polyp growth

- *Acceleration of Neoplastic Growth*

Based on the pharmacologic activity and findings in animals, GATTEX has the potential to cause hyperplastic changes including neoplasia. In patients at increased risk for malignancy, the clinical decision to use GATTEX should be considered only if the benefits outweigh the risks. In patients with active gastrointestinal malignancy (GI tract, hepatobiliary, pancreatic), GATTEX therapy should be discontinued. In patients with active non-gastrointestinal malignancy, the clinical decision to continue GATTEX should be made based on risk-benefit considerations.

- *Colorectal Polyps*

Colorectal polyps were identified during the clinical trials. Colonoscopy of the entire colon with removal of polyps should be done within 6 months prior to starting treatment with GATTEX. A follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies should be done every 5 years or more often as needed. If a polyp is found, adherence to current polyp follow-up guidelines is recommended. In case of diagnosis of colorectal cancer**,** GATTEX therapy should be discontinued.

- *Small Bowel Neoplasia*

Based on benign tumor findings in the rat carcinogenicity study, patients should be monitored clinically for small bowel neoplasia. If a benign neoplasm is found, it should be removed. In case of small bowel cancer, GATTEX therapy should be discontinued.

Gastrointestinal obstruction

Intestinal obstruction has been reported in clinical trials. In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued while the patient is clinically managed. GATTEX may be restarted when the obstructive presentation resolves, if clinically indicated.

Biliary and pancreatic disorders

- *Gallbladder and Biliary Tract Disease*

Cholecystitis, cholangitis, and cholelithiasis, have been reported in clinical studies. For identification of the onset or worsening of gallbladder/biliary disease, patients should undergo laboratory assessment of bilirubin and alkaline phosphatase within 6 months prior to starting GATTEX, and at least every 6 months while on GATTEX; or more frequently if needed. If clinically meaningful changes are seen, further evaluation including imaging of the gallbladder and/or biliary tract is recommended; and the need for continued GATTEX treatment should be reassessed

- *Pancreatic Disease*

Pancreatitis has been reported in clinical studies. For identification of onset or worsening of pancreatic disease, patients should undergo laboratory assessment of lipase and amylase within 6 months prior to starting GATTEX, and at least every 6 months while on GATTEX; or more frequently if needed. If clinically meaningful changes are seen, further evaluation such as imaging of the pancreas is recommended; and the need for continued GATTEX treatment should be reassessed.

Appropriate Patient Selection, Counseling, and Monitoring

Prescribers should select the appropriate patients to receive GATTEX in accordance with the approved prescribing information, discuss the benefits and risks of GATTEX with patients, and monitor patients as specified in the approved prescribing information. A What You Need to Know About Gattex Treatment: A Patient and Caregiver Counseling Guide is available for your use in discussing GATTEX with patients. The guide can be accessed via www.GATTEXREMS.com or by contacting 1-855-5GATTEX (1-855-542-8839).

GATTEX Healthcare Provider Training

It is important that healthcare providers understand the serious risks associated with GATTEX. As part of the REMS, healthcare providers should access www.GATTEXREMS.com to review the Prescriber Education Slide Deck and complete a Post-training Knowledge Assessment. The Prescriber Education Slide Deck and the Post-training Knowledge Assessment can also be obtained in hard copy by contacting 1-855-5GATTEX (1-855-542-8839).

Reporting Adverse Events

To report all suspected adverse events associated with the use of GATTEX, contact

- NPS Pharmaceuticals, toll-free GATTEX Support Line at 1-855-5GATTEX (1-855-542-8839) or Event/Product Complaint Line at 1-855-215-5550,
- FDA MedWatch program at 1-800-FDA-1088 (1-800-332-1088), or via the FDA website at www.fda.gov/medwatch./report.htm

A copy of the letter is available at www. GATTEXREMS.com and through NPS Medical Information (1-855-5GATTEX or 1-855-542-8839). For more information regarding GATTEX, please contact the toll-free GATTEX Support Line at 1-855-5GATTEX (1-855-542-8839) or visit the product website at www.GATTEX.com.

Please see the enclosed full Prescribing Information for GATTEX for additional safety information.

Sincerely,

Roger Garceau, M.D.
Chief Medical Officer
NPS Pharmaceuticals, Inc.

Enclosures:

- GATTEX Full Prescribing Information
- Medication Guide

GATTEX Dear Professional Society Letter

[Date]

IMPORTANT DRUG WARNING

Subject: Risk of possible acceleration of neoplastic growth and enhancement of colon polyp growth, GI obstruction, biliary and pancreatic disorders with GATTEX® (teduglutide)

Dear Professional Society Leader:

The purpose of this letter is to remind you about the serious risks associated with GATTEX® (Teduglutide [rDNA origin]) for Injection and need for continuous monitoring for these risks.

Gattex is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of GATTEX outweigh the potential risks. The REMS includes a healthcare provider education and training.

We are sending your organization this communication to distribute to members of your organization who may be appropriate prescribers of Gattex.

Serious Risks of Gattex

Possible acceleration of neoplastic growth and enhancement of colon polyp growth

- *Acceleration of Neoplastic Growth*

Based on the pharmacologic activity and findings in animals, GATTEX has the potential to cause hyperplastic changes including neoplasia. In patients at increased risk for malignancy, the clinical decision to use GATTEX should be considered only if the benefits outweigh the risks. In patients with active gastrointestinal malignancy (GI tract, hepatobiliary, pancreatic), GATTEX therapy should be discontinued. In patients with active non-gastrointestinal malignancy, the clinical decision to continue GATTEX should be made based on risk-benefit considerations.

- *Colorectal Polyps*

Colorectal polyps were identified during the clinical trials. Colonoscopy of the entire colon with removal of polyps should be done within 6 months prior to starting treatment with GATTEX. A follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies should be done every 5 years or more often as needed. If a polyp is found, adherence to current polyp follow-up guidelines is recommended. In case of diagnosis of colorectal cancer**,** GATTEX therapy should be discontinued.

- *Small Bowel Neoplasia*

Based on benign tumor findings in the rat carcinogenicity study, patients should be monitored clinically for small bowel neoplasia. If a benign neoplasm is found, it should be removed. In case of small bowel cancer, GATTEX therapy should be discontinued.

Gastrointestinal obstruction

Intestinal obstruction has been reported in clinical trials. In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued while the patient is clinically managed. GATTEX may be restarted when the obstructive presentation resolves, if clinically indicated.

Biliary and pancreatic disorders

- *Gallbladder and Biliary Tract Disease*

Cholecystitis, cholangitis, and cholelithiasis, have been reported in clinical studies. For identification of the onset or worsening of gallbladder/biliary disease, patients should undergo laboratory assessment of bilirubin and alkaline phosphatase within 6 months prior to starting GATTEX, and at least every 6 months while on GATTEX; or more frequently if needed. If clinically meaningful changes are seen, further evaluation including imaging of the gallbladder and/or biliary tract is recommended; and the need for continued GATTEX treatment should be reassessed

- *Pancreatic Disease*

Pancreatitis has been reported in clinical studies. For identification of onset or worsening of pancreatic disease, patients should undergo laboratory assessment of lipase and amylase within 6 months prior to starting GATTEX, and at least every 6 months while on GATTEX; or more frequently if needed. If clinically meaningful changes are seen, further evaluation such as imaging of the pancreas is recommended; and the need for continued GATTEX treatment should be reassessed.

Appropriate Patient Selection, Counseling, and Monitoring

Prescribers should select the appropriate patients to receive GATTEX in accordance with the approved prescribing information, discuss the benefits and risks of GATTEX with patients, monitor patients as specified in the approved prescribing information and report adverse events to NPS Pharmaceuticals.

GATTEX Healthcare Provider Training

It is important that healthcare providers understand the serious risks associated with GATTEX. As part of the REMS, healthcare providers should access www.GATTEXREMS.com to review the Prescriber Education Slide Deck and complete a Post-training Knowledge Assessment. The Prescriber Education Slide Deck and the Post-training Knowledge Assessment can also be obtained in hard copy by contacting 1-855-5GATTEX (1-855-542-8839).

Reporting Adverse Events

To report all suspected adverse events associated with the use of GATTEX, contact

- NPS Pharmaceuticals, toll-free GATTEX Support Line at 1-855-5GATTEX (1-855-542-8839) or Event/Product Complaint Line at 1-855-215-5550,
- FDA MedWatch program at 1-800-FDA-1088 (1-800-332-1088) or via the FDA website at www.fda.gov/medwatch./report.htm

A copy of the letter is available at www. GATTEXREMS.com or via NPS Medical Information (1-855-5GATTEX).

Should your members require additional information about GATTEX, please direct them to contact the toll-free GATTEX Support Line at 1-855-5GATTEX (1-855-542-8839) or visit the product website at www.GATTEX.com.

Please see the enclosed full Prescribing Information for GATTEX for additional safety information.

Sincerely,

Roger Garceau, M.D.
Chief Medical Officer
NPS Pharmaceuticals, Inc.

Enclosures:

- GATTEX full Prescribing Information
- Medication Guide

Prescriber Education Slide Deck

GATTEX® (Teduglutide [rDNA origin]) for Injection REMS Program: Prescriber Education

NPS Pharmaceuticals, Inc.
550 Hills Drive, Bedminster, NJ 07921

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. The GATTEX Prescriber Education Slide Deck is required by the FDA as part of the GATTEX REMS Program.

Gattex® (Teduglutide [rDNA origin]) for Injection

GTX-044-0614

Table of Contents

Gattex® (Teduglutide [rDNA origin]) for Injection

Indication

- GATTEX® (teduglutide [rDNA origin]) for injection is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.
- Teduglutide is a recombinant analog of GLP-2

GLP-2, glucagon-like peptide-2

Gattex® (Teduglutide [rDNA origin]) for Injection

Overview
Important Adverse Reactions of Special Interest

- Possible safety risks with GATTEX
  - Possible acceleration of neoplastic growth and enhanced growth of colorectal polyps
  - Gastrointestinal obstruction
  - Gallbladder, biliary tract and pancreatic disease
  - Increased absorption of fluids leading to fluid overload in patients with cardiovascular disease
  - Increased absorption of oral medications with narrow therapeutic index

Gattex® (Teduglutide [rDNA origin]) for Injection

Possible Acceleration of Neoplastic Growth

- GLP-2 receptors are localized mainly in the GI tract[1]
- GATTEX promotes growth of intestinal epithelial cells in the GI tract
- It can not be excluded that GATTEX promotes growth of existing neoplasms in the GI tract
- 3 patients on GATTEX were reported with neoplasms*:
  - 2 cases of lung cancer with smoking history
  - 1 case of GI metastatic adenocarcinoma (unknown origin) following abdominal radiation for Hodgkin's disease

1. Munroe DG et al. Proc Natl Acad Sci. 1999; 96:1569-1573.
* As of January 24, 2013

Gattex® (Teduglutide [rDNA origin]) for Injection

Possible Acceleration of Neoplastic Growth
GATTEX Label – Warnings and Precautions

Possible Acceleration of Neoplastic Growth

- Based on the pharmacologic activity and findings in animals, GATTEX has the potential to cause hyperplastic changes including neoplasia.
- Based on benign tumor findings in the rat carcinogenicity study, patients should be monitored clinically for small bowel neoplasia. If a benign neoplasm is found, it should be removed. In case of small bowel cancer, GATTEX therapy should be discontinued.
- In patients with active gastrointestinal malignancy (GI tract, hepatobiliary, pancreatic), GATTEX therapy should be discontinued.
- In patients with active non-gastrointestinal malignancy, the clinical decision to continue GATTEX should be made based on risk-benefit considerations.
- In patients at increased risk for malignancy, the clinical decision to use GATTEX should be considered only if the benefits outweigh the risks.

Gattex® (Teduglutide [rDNA origin]) for Injection

Possible Enhanced Growth of Colorectal Polyps

- 11/173 (6.4%) GATTEX-treated patients developed GI polyps in pooled Phase III SBS studies*
  - 2 villous adenomas
  - 3 hyperplastic
  - 3 tubular adenomas
  - 1 serrated adenoma
  - 1 inflammatory
  - 1 biopsy not done
- GATTEX mechanism of action and nonclinical data are consistent with a potential to enhance growth of polyps

* As of January 24, 2013

Gattex® (Teduglutide [rDNA origin]) for Injection

Possible Enhanced Growth of Colorectal Polyps
GATTEX Label – Warnings and Precautions

Colorectal Polyps

- Colonoscopy of the entire colon with removal of polyps should be done within 6 months prior to starting treatment with GATTEX.
- A follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX.
- Subsequent colonoscopies should be done every 5 years or more often as needed. If a polyp is found, adherence to current polyp follow-up guidelines is recommended.
- In case of diagnosis of colorectal cancer, GATTEX therapy should be discontinued.

Gattex® (Teduglutide [rDNA origin]) for Injection

Gastrointestinal Obstruction

- 12 patients experienced one or more episodes of intestinal obstruction/stenosis*
  - 6 in SBS placebo-controlled studies
    - 3/77 (3.9%) on GATTEX, 0.05 mg/kg/day
    - 3/32 (9.4%) on GATTEX, 0.10 mg/kg/day
    - None in placebo-group
    - Onset 1 day to 6 months
  - 6 in the extension studies (all on GATTEX, 0.05 mg/kg/day)
    - Onset 6 days to 19 months
    - Of all of these patients, 2 patients required endoscopic dilatation; and one required surgical intervention

* As of January 24, 2013

Gattex® (Teduglutide [rDNA origin]) for Injection

Gastrointestinal Obstruction
GATTEX Label – Warnings and Precautions

Intestinal Obstruction

- Intestinal obstruction has been reported in clinical trials.
- In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued while the patient is clinically managed.
- GATTEX may be restarted when the obstructive presentation resolves, if clinically indicated.

Gattex® (Teduglutide [rDNA origin]) for Injection

Gallbladder and Biliary Tract Disease

- 13/173 (7.5%) of GATTEX-treated patients reported biliary events, including cholecystitis and gallstones/sludge in pooled Phase III SBS studies*
  - 5 patients had a history of biliary disease
  - None of these events resulted in study withdrawal

* As of January 24, 2013

Gattex® (Teduglutide [rDNA origin]) for Injection

Gallbladder and Biliary Tract Disease
GATTEX Label – Warnings and Precautions

Gallbladder and Biliary Tract Disease

- Cholecystitis, cholangitis, and cholelithiasis have been reported in clinical studies.
- Patients should undergo initial (within 6 months prior) laboratory assessment of bilirubin and alkaline phosphatase.
- Subsequent laboratory assessments are recommended every 6 months; if a clinically meaningful elevation is seen imaging of the biliary tract is recommended to identify possible obstruction.

Gattex® (Teduglutide [rDNA origin]) for Injection

Pancreatic Disease

- 3/173 (1.7%) of GATTEX-treated patients developed pancreatitis in pooled Phase III SBS studies*
  - All 3 patients had a history of pancreatitis
  - None of these events resulted in study withdrawal

* As of January 24, 2013

Gattex® (Teduglutide [rDNA origin]) for Injection

Pancreatic Disease
GATTEX Label – Warnings and Precautions

Pancreatic Disease

- Pancreatitis has been reported in clinical studies.
- Patients should undergo initial (within 6 months prior) laboratory assessment of lipase and amylase.
- Subsequent laboratory assessments are recommended every 6 months; if a clinically meaningful elevation is seen imaging of the pancreas is recommended to identify possible obstruction.

Gattex® (Teduglutide [rDNA origin]) for Injection

Fluid Overload

- 23/173 (13.3%) of patients treated with GATTEX reported fluid overload in pooled Phase III SBS studies*
- Fluid overload should be considered when administering GATTEX in patients with underlying heart disease

* As of January 24, 2013

Gattex® (Teduglutide [rDNA origin]) for Injection

Fluid Overload
GATTEX Label – Warnings and Precautions

Cardiovascular Disease

- Due to increased intestinal fluid absorption, patients with cardiovascular disease, such as cardiac insufficiency and hypertension, should be monitored with regard to fluid overload, especially during initiation of therapy.
- Parenteral nutrition/intravenous (PN/IV) fluid volume should be reassessed relative to signs of fluid overload.
- In case of a significant deterioration of the cardiovascular disease, the need for continued GATTEX treatment should be reassessed.

Gattex® (Teduglutide [rDNA origin]) for Injection

PN/IV Volume Adjustment

- In order to reduce risk for fluid overload the following PN/IV volume adjustment algorithm is suggested
  - Determine pre-treatment urine output (ideally 1 to 2 L/day)
  - Determine urine output 2 to 4 weeks after starting treatment
  - Reduce weekly PN/IV volume by 10% to 30% if urine output increased at least 10% compared with pre-treatment volume
  - Evaluate if the patient tolerated the PN/IV reduction 1 to 2 weeks later
  - Continue monitoring urine output on a regular basis and adjust PN/IV volume accordingly with the goal of reducing or achieving complete independence from PN/IV support and maintaining clinical nutrition status

Gattex® (Teduglutide [rDNA origin]) for Injection

Increased Absorption of Concomitant Oral Medication

- Based on the pharmacodynamic effect of GATTEX, there is a potential for increased absorption of concomitant oral medications
- Considerations should be given for dosage adjustment of concomitant oral medication requiring titration or that have a narrow therapeutic index

Gattex® (Teduglutide [rDNA origin]) for Injection

Increased Absorption of Concomitant Oral Medication GATTEX Label – Warnings and Precautions

Risks Resulting from Increased Absorption of Concomitant Oral Medication

- Altered mental status in association with GATTEX has been observed in patients on benzodiazepines in clinical trials.
- Patients on concomitant oral drugs (e.g., benzodiazepines, phenothiazines) requiring titration or with a narrow therapeutic index may require dose adjustment while on GATTEX.

Gattex® (Teduglutide [rDNA origin]) for Injection

What You Need to Know About Gattex Treatment: A Patient and Caregiver Counseling Guide

What You Need to Know About GATTEX® Treatment:

A Patient & Caregiver Counseling Guide

Patients:

Your doctor or nurse will go over this Patient & Caregiver Counseling Guide with you. Make sure you ask any questions that you may have about GATTEX. Keep this guide for important safety information about the serious risks and reactions of GATTEX.

Healthcare Providers:

Review this Patient & Caregiver Counseling Guide with your patient each time and provide your patient a copy to take home.

Gattex®
(Teduglutide [rDNA origin]) for Injection

Reference ID: 3532895

What is GATTEX®?

GATTEX is a medicine used in adults with Short Bowel Syndrome (SBS) who need extra nutrition or fluids from intravenous (IV) feeding (parenteral support). It is not known if GATTEX is safe or effective in children.

What Are the Most Serious Risks Related to GATTEX Treatment?

GATTEX can make abnormal cells that are already in your body grow faster.

There is an increased risk that abnormal cells could become cancer. If you get cancer of the bowel (intestines), liver, gall bladder, or pancreas while using GATTEX, your doctor should stop GATTEX treatment. If you get other types of cancers, you and your doctor should discuss the risks and benefits of using GATTEX.

GATTEX may cause polyps in the colon (large intestine). Polyps are growths on the inside of the colon.

BEFORE you start GATTEX, your doctor will:	**AFTER** you start GATTEX, your doctor will:
✓ Check your colon for polyps within 6 months before starting GATTEX. ✓ Remove all polyps.	✓ Check your colon for new polyps at the end of 1 year of using GATTEX. If no polyp is found, your doctor should check you for polyps as needed and at least every 5 years. ✓ Remove any new polyps. If cancer is found in a polyp, your doctor should stop GATTEX treatment.

GATTEX may prevent food, fluids, and gas from moving through your bowels (intestines) in a normal way. Tell your doctor if you have any of these symptoms that could be a sign of blockage of the bowel:

- trouble having a bowel movement or passing gas
- stomach area (abdomen) pain or swelling
- nausea
- vomiting
- swelling and blockage of your stoma opening, if you have a stoma

GATTEX can cause swelling (inflammation) or blockage of your gallbladder or pancreas. Your doctor will do tests to check your gallbladder or pancreas within 6 months before starting GATTEX and at least every 6 months while you are using GATTEX. Tell your doctor right away if you get:

- stomach area (abdomen pain)
- chills
- fever
- change in your stools
- nausea
- vomiting
- dark urine
- yellowing of your skin or the whites of eyes

What Can I Do to Help Lower the Risks of GATTEX?

Tell your doctor if you have:

- cancer or a history of cancer
- had polyps anywhere in your bowel (intestines) or rectum
- heart problems
- high blood pressure
- problems with your gallbladder, pancreas, kidneys
- any other medical condition
- Are pregnant or planning to become pregnant. It is not known if GATTEX will harm your unborn baby. Tell your doctor right away if you become pregnant while using GATTEX.
- Are breastfeeding or plan to breastfeed. It is not known if GATTEX passes into your breast milk. You and your doctor should decide if you will use GATTEX or breastfeed. You should not do both.
- Are taking medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using GATTEX with certain other medicines may cause side effects.

Where Can I Get More information on GATTEX?

For more information about GATTEX, visit GATTEXREMS.com. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please read the enclosed Medication Guide in full and ask your doctor if you have any questions.

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Gattex®
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GATTEX REMS Website Screenshots

Gattex®
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GATTEX REMS (Risk Evaluation and Mitigation Strategy)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks. The FDA has required a REMS for GATTEX.

The purpose of the GATTEX REMS is to inform healthcare providers and patients about the following risks:

- Possible acceleration of neoplastic growth and Enhancement of colon polyp growth
- Gastrointestinal obstruction
- Biliary and pancreatic disorders

Prescribers who intend to treat patients with Gattex should review the education materials which are part of the REMS. Post-training Knowledge Assessment Questions, which are not a part of the REMS, are provided to assure successful training before prescribing Gattex.

FOLLOW THE TWO STEP PROCESS BELOW:

1. Review the Prescriber Education Slide Deck
2. Complete your Post-training Knowledge Assessment Questions

FOR HEALTHCARE PROVIDERS

+ Dear Healthcare Professional Letter
+ Dear Professional Society Letter
+ Prescriber Education Slide Deck
+ Post-training Knowledge Assessment Questions
+ Patient & Caregiver Counseling Guide
+ Full Prescribing Information
+ Medication Guide

Gattex®
(Teduglutide [rDNA origin]) for Injection

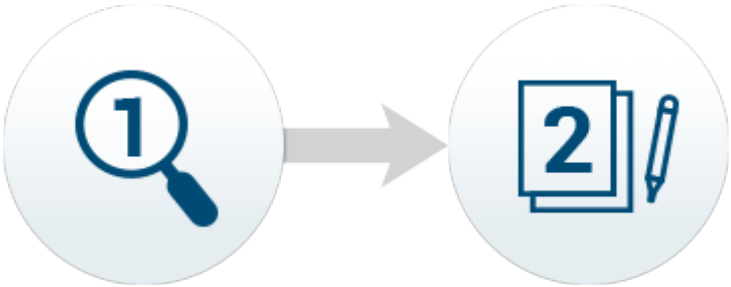
Risk Evaluation and Mitigation Strategy (REMS)

Previous

- Next

You have completed the Prescriber Education Slide Deck.

Next step: Complete your Post-training Knowledge Assessment Questions. Continue



Adobe +Download Printable PDF

+Return to Prescriber Education Slide Deck

Prescriber Training - Welcome

You have selected to take the Post-training Knowledge Assessment Questions for GATTEX.

Before completing your Post-training Knowledge Assessment Questions, you should review the Prescriber Education Slide Deck.

If you have already reviewed the Prescriber Education Slide Deck, please begin the Post-training Knowledge Assessment Questions

Next

Gattex®
(Teduglutide [rDNA origin]) for Injection

Prescriber Training - Identification

NPI:

First Name:

Last Name:

Next

NPS Pharma™
The Nexus of Patients and Science™

You are about to begin the GATTEX Knowledge Assessment.

You will need approximately 10 minutes to complete the assessment. After 20 minutes of inactivity, your session will expire and you will be logged out of the Knowledge Assessment.

You will need to complete the assessment in its entirety from start to finish in order to have your information saved. Please click the start button to begin the Post-training Knowledge Assessment.

Start

Notes:
This is the screen prior to getting to the knowledge assessment

Date: <Completion date>
NPI Number: <NPI Number>
HCP Name: <First Name> <Last Name>

Certificate Completion #: <Certificate Completion Number>

This certificate confirms that you have completed the GATTEX Knowledge Assessment

Please print a copy of this certificate for your records. Once you have printed the certificate, please close the window

Print Certificate

Notes:
After the last question in the Knowledge Assessment, the user will be presented with the following Web page.
Anything list between the characters “<>” will be pulled from a database
When the user clicks Print Certificate, another window will open with the text to be printed.

Date: <Completion date>
NPI Number: <NPI Number>
HCP Name: <First Name> <Last Name>

Certificate Completion #: <Certificate Completion Number>

This certificate confirms that you have completed the GATTEX Knowledge Assessment

Please print a copy of this certificate for your records. Once you have printed the certificate, please close the window

Notes:
Window after the user clicks Print Certificate.